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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,914

09/20/2005

Yasumi Yugari

2005_1461A

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7590

01/27/2011

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EXAMINER

FRAZIER, BARBARA S

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

01/27/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/549,914	Applicant(s) YUGARI ET AL.	
	Examiner BARBARA FRAZIER	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/27/10 has been entered.

Status of Claims

2. Claims 1 and 3-10 are pending in this application. Claim 2 stands canceled.
3. Claims 1 and 3-10 are examined.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **Claims 1 and 3-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

Art Unit: 1611

application was filed, had possession of the claimed invention. Independent claim 1 recites a yeast having a trace metal selected from the group consisting of Mg, Zn, Fe, Cu, Co and Mn (line 8 of claim 1). However, the specification only teaches yeasts with the trace metals Fe, Zn, Cu, Mn, Cr, and Se (page 11, 2nd full paragraph). While the specification teaches that patients with kidney failure or hepatic failure often lack ingestion of trace metals, including Mg (magnesium) and Co (cobalt), the specification does not teach Mg- and Co-containing yeasts. Therefore, the yeasts with the trace metals Mg (magnesium) and Co (cobalt) constitute new matter.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The rejection of claims 1 and 3-10 under 35 USC 103(a) as being unpatentable over Nakashima et al (US Patent 5,126,143) in view of Farmer (US Patent 6,461,607) and FR 2244464 ("FR '464") as evidenced by Lasater et al (US Patent 5,200,218) is withdrawn in view of Applicant's amendment to claim 1; however, a new grounds of rejection is set forth below.

8. **Claims 1 and 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakashima et al (US Patent 5,126,143) in view of Farmer (US Patent 6,461,607) and FR 2244464 ("FR '464"; previously cited), as evidenced by**

**Lasater et al (US Patent 5,200,218), and further in view of Yuan et al
(*Biotechnology Letters*, 26, pp. 311-315, February 2004).**

The claimed invention, as now amended, is drawn to a food composition for lowering blood concentration of low- molecular-weight nitrogen-containing compounds, which comprises: a foodstuff comprising a) more than 5% by weight of water-soluble indigestible polysaccharides relative to a total amount of the foodstuff, said indigestible polysaccharides capable of being decomposed by intestinal bacteria, b) *Bacillus coagulans*, c) a metal-containing yeast comprising 0.01% to 5.0% by weight of a trace metal selected from the group consisting of Mg, Zn, Fe, Cu, Co and Mn relative to the total amount of the foodstuff, and d) a protein component of 8% or less by weight relative to the total amount of the foodstuff (see claim 1).

Nakashima et al teach a bowel-movement-improving food containing 10-50% by weight of dietary fibers based upon the whole product (see claim 1). Nakashima et al. teach foods having more than 5% by weight indigestible polysaccharides; see Example 1, which has 25% dietary fibers (18 parts polydextrose and 6.9 parts pectin, relative to 100.3 total parts). The amount of protein in the food is less than 8%; amounts of 6% and 5.4% casein are exemplified (see, for example, Examples 1 and 4). The dietary fibers are decomposed by intestinal microorganisms (see Examples 1, 4 and 5). Nakashima et al further teach that the food products may also contain minerals, such as iron lactate (col. 4, lines 32-37).

Nakashima et al do not specifically teach the presence of *Bacillus coagulans*; additionally, while Nakashima et al teach the presence of minerals such as iron in its

Art Unit: 1611

composition, Nakashima et al do not specifically that the mineral is in the form of a yeast comprising 0.01% to 5% by weight of the mineral.

Farmer teaches the utilization of lactic acid-producing bacteria, preferably *Bacillus coagulans*, for control of gastrointestinal tract pathogens and their associated diseases (abstract), and that *Bacillus coagulans* strains have been used as general nutritional supplements and agents to control constipation and diarrhea in humans and animals (col. 14, lines 50-53).

FR '464 teaches a composition comprising yeast, a lactobacillus, and B vitamins, for treatment of conditions including constipation and digestive disorders (see 4th, 8th, and 10th-15th paragraphs of the translation); the yeast is preferably *Saccharomyces cerevisiae* (i.e., Brewer's yeast; see 6th paragraph of the translation). Brewer's yeast is a metal-containing yeast comprising metals such as iron; as evidence, Lasater et al generally teach that Brewer's yeast includes iron (col. 2, lines 56-63). FR '464 does not specifically teach the amount of iron in the Brewer's yeast.

Yuan et al teach an iron-enriched yeast strain of *Saccharomyces cerevisiae* (i.e., Brewer's yeast) with a higher biomass (page 311). The amount of iron contained in the yeast cells is up to 25 mg/g (2.5%), whereas the amount of iron in normal Brewer's yeast is 60-200 µg/g (0.0006-0.02%) (page 314). Yuan et al teach that its iron-enriched yeast possesses higher ability to accumulate and convert iron, and has the potential use in industrial processes as an iron-fortified food supplement and feed additive for human and animal (pages 314-315).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add *Bacillus coagulans* and metal-containing yeast to the composition of Nakashima et al; thus arriving at the claimed invention. One skilled in the art would have been motivated to add *Bacillus coagulans* because the addition of *Bacillus coagulans* provides the benefits of controlling constipation and diarrhea, as taught by Farmer. Additionally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art, to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. See MPEP 2144.06. Additionally, since metal containing yeast is known to be useful in compositions for treating constipation, as taught by FR '464, one skilled in the art would be motivated to add metal containing yeast in order to provide additional nutritional benefits, as well as providing the benefit of treating constipation and other digestive disorders, as taught by FR '464. Furthermore, since Yuan et al teach that its iron in the form of iron-enriched yeast possesses higher ability to accumulate and convert iron, and has the potential use in industrial processes as an iron-fortified food supplement and feed additive for human and animal, one skilled in the art would be motivated to substitute the normal Brewer's yeast taught by FR '464 with the iron-enriched yeast of Yuan et al in order to further improve the nutritional content of the resultant composition.

Regarding the phrase "for lowering blood concentration of low-molecular-weight nitrogen-containing compounds", said phrase describes an intended use for the food and does not provide any structural limitation to the composition, and thus is not given patentable weight.

Regarding claim 3, Nakashima et al. disclose that dietary fibers which may be used are polydextrose and pectin (see col. 3, lines 20-22 and claim 1).

Regarding claim 4, Nakashima et al. disclose that the food contains a mixture of polydextrose and pectin, wherein said mixture is comprised of 1/2 to 3/4 polydextrose and 1/2 to 1/4 pectin. This reads on Applicant's ratio of 0.05 to 100 parts by weight of pectine to 100 parts of polydextrose.

Regarding claims 5 and 6, Nakashima et al. disclose that the foods may contain vitamins (col. 4, lines 32-38).

Regarding claims 7-10, Nakashima et al. disclose that the food may be in the form of the wafer; the term "wafer" reads on a reasonable interpretation of either "biscuit", "cookie" or "bread".

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Response to Arguments

9. Applicant's arguments with respect to claims 1 and 3-10 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1611

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Ashwin Mehta/
Primary Examiner, Technology Center 1600